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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,892	11/26/2007	Antti Haapalinna	06267.0132	4440

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EXAMINER	
RAO, SAVITHA M	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
04/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,892	HAAPALINNA ET AL.	
	Examiner	Art Unit	
	SAVITHA RAO	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *3-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/26/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7 are pending.

Claims 3-6 are withdrawn from consideration as being drawn towards nonelected specie.

Claims 1, 2 and 7 are under consideration in the instant office action.

Election/Restrictions

Applicant's election with traverse of atipamezole as the single discloses specie of alpha2-adrenoceptor antagonist in the reply filed on 02/03/2009 is acknowledged. The traversal is on the ground(s) that the there is unity of invention among the speices under the PCT 13.1 standard rule. While the applicant does not provide any arguments in response to the lack of unity argument presented by the exaiminer in the restriction requirement dated 01/05/2009 page 2, applicants arguments raised against the art presented in the international search report to argue presences of unity among the speices is unpersuasive. Additionally, these arguments are against the art not yet raised by the examiner (as noted by the applicant on page 2 of the response) and therefore not given consideration by the examiner.

Therefore, Examiner finds the applicant's argument unpersuasive and maintains the restriction since as the species are patentably distinct and independent since they lack unity as set forth in the restriction requirement dated 01/05/2009 (pages 2). The subject matter clearly lacks unity of invention for the reasons given in the restriction requirement and, thus, the claims are directed to patentably distinct inventions and,

thus, do not constitute overlapping subject matter that would result in a coextensive search.

Thereby the restriction requirement is still deemed proper and is therefore made FINAL.

Claims under consideration in the current office action are claims 1,2 and 7. Claims 3-6 are withdrawn from cancellation as being drawn to unelected specie. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/03/2009

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the “a patient at risk of developing epilepsy” are unclear. The term “a patient at risk of developing epilepsy” is unclear because there is no clear definition as to which type of patients are under risk of developing epilepsy in the instant disclosure". The specification does not clarify the patient population in terms of rodent population or human population, male or female population, age group of the population etc. and accordingly claim1 and dependent claim 2 is unclear as to who the patient population is.

Instant claim 7 and the instant disclosure states on page 3, 2nd paragraph that the instantly claimed method involves treatment of patients with initial brain damaging insult like head trauma, brain ischemia and infection or neurosurgical operation and the examination of the claim 1 and 2 will be conducted to the extent it reads on “the patient at risk of developing epilepsy" as being any subjects which has undergone initial brain damaging insult like head trauma, brain ischemia and infection or neurosurgical operation

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 7 are ejected under 35 U.S.C. 102(b) as being anticipated by Puurunen et al (Neuropharmacology 40 (2001) 597-606)

Puurunen et al. discloses whether systemic administration of atipamezole, facilitates recovery following transient focal cerebral ischemia in rats (abstract) Puurunen et al. discloses that atipamezole rapidly penetrates the brain and increases the release of central noradrenaline. Puurunen et al. also discloses that atipamezole is a potent alpha2-adrenoceptor antagonist with a high alpha2/alpha1 selectivity ratio with negligible affinity for other receptors such as 5-HT and imidazoline receptors (page 598, left col., 2nd paragraph). Puurunen et al. discloses brain ischemic induction in rats and treatment of these rats with atipamezole hydrochloride in sterile water administered

once a day (1 mg/kg subcutaneously), beginning on day 2 of the ischemic induction and continuing for 10 days (page .598, methods, sections 2.1 and 2.2). Puurunen et al. discloses that atipamezole is well –tolerated over a wide range of doses and that atipamezole improve behavioral performance of ischemic rats and accordingly provides a promising pharmaceutical approach to facilitate the recovery process following cerebral ischemia (page 604, right col., last paragraph)

"Though it is noted that Puurunen et al. does not administer atipamezole to inhibit development of epilepsy, the teaching by Puurunen of the method comprising administration of atipamezole to a patient with brain ischemia, is the same as the method currently claimed, and thus renders the instant claims anticipatory. The effective dose of the compound as disclosed by Puurunen which is 1 mg/ kg of the patient subcutaneously is anticipatory of the effective dose in the instant application as disclosed in the instant disclosure page 2, last paragraph to page 3, first paragraph. It is also noted that "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Puurunen et. al discloses the instantly claimed compounds administered to the instantly claimed patient population. As such the instantly claimed mechanistic functions of the compounds to inhibit the development of epilepsy would be present in the identical compound taught by Puurunen et al.

administered to identical patient population and would therefore elicit these effects whenever it is administered.

Accordingly claims 1, 2 and 7 are anticipated by Puurunen et al.

Conclusion

Claims 1-2 and 7 are rejected. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7 am to 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614